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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,813	12/10/1999	Brian R. Murphy	17634-000330US	9312

7590 10/02/2003

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EXAMINER

CHEN, STACY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,813

Applicant(s)

MURPHY ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-45 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) 27-33 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-26,34-45,47,51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2003 has been entered.
2. Claims 1-6, 8-45 and 47-52 are pending. Claims 1-6, 8-26, 34-45, 47 and 51-52 are examined.

Response to Arguments

3. The Murphy Declaration, submitted April 30, 2003, and Applicant's arguments have been carefully considered. The rejections hinging on the enablement/non-enablement of Belshe (5,869,036) are addressed in the Declaration. The Office agrees that Belshe fails to show any working examples of recovery of recombinant PIV from cDNA. Dr. Murphy attributes this failure to many deficiencies in Belshe. A notable deficiency is that Belshe fails to provide an accurate sequence of a wild type PIV. Further, Belshe's PIV3 sequence was taken from published sequences of others, which were found to contain errors and lacked identification of many major attenuating mutations. Applicants have corrected the errors in the sequence of the wild type PIV and identified major attenuating mutations. Applicants have provided exact lengths of a full length cDNA for PIV3 that take into account the "rule of six", not disclosed by Belshe as a critical factor in recovery of authentic copies of virus without random mutations.

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Despite these notable differences between Belshe and Applicant's invention, *all pending are rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) are maintained for reasons of record* and in view of the following:

The instant claims are drawn to an isolated, infectious, chimeric PIV comprising an HPIV vector genome or antigenome combined with an antigenic determinant from HPIV1 and/or HPIV2 to form a chimeric PIV genome or antigenome. While the method with which Belshe recovers cp45 virus (from L-gene-transfected CCV-1 cells, see Example 6 of Belshe) is not the same as Applicant's recovery of PIV from cDNA, the claims are drawn to products. The process by which the virus is obtained does not render the virus novel.

Double Patenting

4. Claims 1-6, 8-26, 34-45, 47 and 51-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 105-111, 127-128, 141 and 143 of copending Application No. 09/458,813. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the co-pending application are a species of the instant claims. The instant claims are drawn to an isolated chimeric PIV comprising a partial or complete HPIV3 JS vector genome or antigenome, combined with one or more heterologous genes or genome segments encoding antigenic determinants (HN, F) of HPIV 1 and/or HPIV2. The claims of the co-pending application are drawn to an isolated PIV particle comprising a recombinant HPIV genome which incorporated a mutations from JScp45.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

5. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

sbc

Stacy B. Chen
September 23, 2003

James C. Housel
JAMES HOUSEL 10/1/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600